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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,320	03/28/2001	Henry E. Young	1304-1-019 CIP1	4118

7590 10/03/2002

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EXAMINER
TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,320	YOUNG ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The prior Restriction, mailed 6/6/02, Paper No. 7 is vacated and a new restriction appears below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5, 8-17, drawn to pluripotent embryonic-like stem cells, methods of isolating pluripotent embryonic-like stem cell lines, classified in class 435, subclass 325, for example.

II. Claim 4, drawn to a pluripotent endodermal stem cell, classified in class 435, subclass 325, for example.

III. Claim 6, drawn to a pluripotent ectodermal stem cell, classified in class 435, subclass 325, for example.

IV. Claim 7, drawn to an endodermal, ectodermal, or mesodermal lineage-committed cell, classified in class 435, subclass 325, for example.

V. Claims 18-20, drawn to methods of screening agents which are lineage commitment factors, classified in class 435, subclass 4, for example.

VI. Claims 21-23, drawn to methods for screening agents which are proliferation factors, classified in class 435, subclass 4, for example.

VII. Claims 24-32, drawn to methods of cellular transplantation, and pharmaceutical compositions for cellular transplantation, classified in class 424, subclass 93.1, and class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and any of Inventions II-IV are mutually exclusive and independent inventions. The pluripotent embryonic-like stem cells of Invention I

are not required for the pluripotent endodermal stem cell of Invention II, the pluripotent ectodermal stem cell of Invention III, or for the endodermal, ectodermal or mesodermal lineage-committed cell of Invention IV, and vice versa. Furthermore, each of the inventions is directed to different types of cells which are not obvious variants of each other.

Inventions I and any of Inventions V-VII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the embryonic-like stem cells of Invention I can be used to make transgenic animals.

Invention II and any of Inventions III-VII are mutually exclusive and independent. The pluripotent endodermal stem cell of Invention II is not required for the pluripotent ectodermal stem cell of Invention III, the endodermal, ectodermal or mesodermal lineage-committed cell of Invention IV, the method of screening agents which are lineage commitment factors of Invention V, the methods for screening agents which are proliferation factors of Invention VI, or for the implementation of the methods of cellular transplantation of Invention VII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention III and any of Inventions IV-VII are mutually exclusive and independent. The pluripotent ectodermal stem cell of Invention III is not required for the endodermal, ectodermal or mesodermal lineage-committed cell of Invention IV, the method of screening agents which are lineage commitment factors of Invention V, the methods for screening agents which are proliferation factors of Invention VI, or for the implementation of the methods of cellular transplantation of Invention VII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention IV and any of Inventions V-VII are mutually exclusive and independent. The endodermal, ectodermal or mesodermal lineage-committed cell of Invention IV is not required for the implementation of the method of screening agents which are lineage commitment factors of Invention V, the methods for screening agents which are proliferation factors of Invention VI, or for the implementation of the methods of cellular transplantation of Invention VII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention V and either of Inventions VI-VII are mutually exclusive and independent. The method of screening agents which are lineage commitment factors of Invention V is not required for the methods for screening agents which are proliferation factors of Invention VI, or for the implementation of the methods of

cellular transplantation of Invention VII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention VI and Invention VII are mutually exclusive and independent. The methods for screening agents which are proliferation factors of Invention VI, are not required for the implementation of the methods of cellular transplantation of Invention VII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Deborah Crouch

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